**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF RHODE ISLAND**

RONDA KAUFMAN, on behalf of herself
and all others similarly situated,
Plaintiffs

v. C.A. No. 14-216-ML

CVS CAREMARK CORPORATION and
CVS PHARMACY, INC.,
Defendants.

**ORDER AND MEMORANDUM**

The plaintiff in this action, Ronda Kaufman ("Kaufman") has brought claims[1] against CVS Pharmacy, Inc. ("CVS") and its holding company, CVS Caremark Corporation ("CVS Caremark", together with CVS, the "Defendants"), related to the allegedly fraudulent labeling of CVS-brand vitamin E supplements. The matter before the Court is the Defendants' motion to dismiss the complaint. For the reasons that follow, the Defendants' motion is GRANTED.

## I. Factual Background

Kaufman asserts that, on an unspecified date, she purchased

[1] Kaufman's complaint (the "Complaint") is styled as a Class Action Complaint and, as part of her requested remedies, she seeks an order "that this action may be maintained as a Class Action under Rule 23 of the Federal Rules of Civil Procedure, that Plaintiff be appointed to represent for the [national] Class and [Rhode Island and New York] subclass, and that Plaintiff's counsel be appointed as counsel for the Class and subclass." Complaint at 14.

CVS vitamin E 400 IU Softgels (100 count) at a CVS located in Plainview, New York. According to Kaufman, "[p]rior to making her purchases, [she] read and reviewed the representation regarding heart health made on the product packing and, in reliance upon those statements," she bought the supplement. Complaint at 3. Kaufman further alleges that she believed the supplement would "provide the promised heart health benefits" and that, "[a]s a result of her purchases," she "suffered injury in fact and lost money." Id. Finally, Kaufman asserts that she would not have purchased the supplement, "had she known the truth about Defendant's misrepresentations and omissions." Id. It is unstated whether Kaufman actually consumed any of the supplements or whether she has any concerns regarding her risk of heart health. In essence, Kaufman's claim is based on the assertion that CVS's deceptive marketing caused her to lose money.

According to the Complaint, in addition to the product purchased by Kaufman, six other CVS vitamin E supplements (one vitamin E oil preparation and five different softgel capsules) feature a "Heart Health" label on the front, see depiction on page 4 of the Complaint. In addition, the soft gel bottles contain the statement "Vitamin E helps maintain healthy blood vessels and promotes heart health." Complaint at 5. As evident from the complete label provided by CVS in its memorandum in

support of its motion to dismiss (Dkt. No. 10), that statement is followed by another statement that "Vitamin E also supports the immune system," both of which are marked with asterisks, as are the term "Heart Health" and the phrase "Supports Antioxidant Health." In a separate text box, the asterisks are explained as follows: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease." CVS Mem. at 4. The same label also indicates that the product is subject to a "CVS Quality Money Back Guarantee." Id.

Based on the information provided on the label, Kaufman asserts that she was "misled by Defendants' statements to believe its vitamin E products would reduce her risk of heart disease when they do not." Complaint at 7. Kaufman's assertion that Defendants misrepresented the benefit of their products is based on (1) a selection of seven medical journal articles referenced in her Complaint and subsequently submitted to this Court; and (2) the unsupported contention that other, unnamed studies "finding any benefit to consuming vitamin E are generally either epidemiological, flawed, or are findings that occurred by chance." Complaint at 7. Kaufman claims that "[a]s a result of Defendants' deceptive marketing, [she] and other consumers suffered injury in fact and lost money or property." Complaint at

7.

**II. Procedural History**

On May 2, 2014, Kaufman filed a three-count Complaint, alleging (Count I) violation of the Rhode Island Deceptive Trade Practices Act, R.I. Gen. Laws § 6-13.1 et seq.[2]; (Count II) violation of the New York Consumer Protection Act ("NYCPA"), codified at New York General Business Law § 349; and (Count III) Unjust Enrichment/Restitution. Kaufman brings the action on her own behalf and on behalf of (1) a proposed class of United States residents who purchased CVS vitamin E products featuring a "heart health" label or stating that "Vitamin E helps maintain healthy blood vessels and promotes heart health;" and (2) two subclasses of (a) Rhode Island[3] and (b) New York State residents, who made such purchases. In addition to class certification, Kaufman seeks a permanent injunction against the Defendants; disgorgement of profits; actual, statutory, and punitive damages; attorneys' fees, costs, and prejudgment interest. Complaint at 14.

On August 7, 2014, the Defendants filed a motion to dismiss

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[2] Kaufman subsequently withdrew her claim under the Rhode Island Deceptive Trade Practices Act. Pltf.'s Obj. (Dkt. No. 11) at Page 8 of 27 n.1. It remains undisputed that the single transaction on which Kaufman's claims are based took place in the State of New York.

[3] See n. 2 herein.

(Dkt. No. 9) the Complaint pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) on the grounds that (1) Kaufman's claims are moot; (2) Kaufman fails to plead a false or fraudulent act; and (3) Kaufman's claims are preempted by Federal Law and/or exempted by the New York Consumer Protection Act. Defs.' Mem. (Dkt. No. 10).

On August 25, 2014, Kaufman filed a response (Dkt. No. 11) in opposition to the Defendants' motion, to which the Defendants filed a reply on September 4, 2014 (Dkt. No. 12).

Following a telephone conference with the parties on October 23, 2014, the Court advised the parties that it would hold Defendants' motion to dismiss the Complaint in abeyance, pending a decision by the First Circuit Court of Appeals in the case of Bais Yaakov of Spring Valley v. Act, Inc., 798 F.3d 46 (1st Cir. 2015).

On August 21, 2015, the First Circuit issued a decision in Bais Yaakov, holding that "a rejected and withdrawn offer of settlement of the named plaintiff's individual claims in a putative class action made before the named plaintiff moved to certify a class did not divest the court of subject matter jurisdiction by mooting the named plaintiff's claims." Bais Yaakov, 798 F.3d at 46. The First Circuit's decision was based on the determination that the defendant's offer did not moot the litigation because the plaintiff had not "received complete

relief." Id. at 55.

Days after the Bais Yaakov opinion was issued, the Defendants submitted an additional briefing to this Court, seeking to distinguish the instant case from the facts in Bais Yaakov (Dkt. No. 13). Kaufman promptly filed a response in opposition (Dkt. No. 15), to which the Defendants filed a reply (Dkt. No. 16). On October 14, 2015, Kaufman filed a motion for leave to file a supplemental brief (Dkt. No. 17) in opposition to the Defendants' motion to dismiss the Complaint. After her motion was granted, Kaufman filed the supplemental brief on October 26, 2015 (Dkt. No. 19). The following day, the Defendants filed a motion for leave to file a response (Dkt. No. 20) to Kaufman's supplemental memorandum. That motion having been granted as well, the Defendants filed a Reply Memorandum on November 17, 2015 (Dkt. No. 22). Finally, on December 10, 2015, Kaufman filed a motion for a hearing (Dkt. No. 23) on the Defendants' motion to dismiss her Complaint. However, given the extensive and thorough briefing the Defendants' motion has generated, the Court is of the opinion that no such hearing is necessary and proceeds to render a decision without oral argument.

**III. Standard of Review**

A motion to dismiss for lack of subject matter jurisdiction is governed by Fed. R. Civ. P. 12(b)(1). A motion to dismiss for

failure to state a claim upon which relief may be granted is governed by Fed. R. Civ. P. 12(b)(6). If a motion is brought under both 12(b)(1) and 12(b)(6), "a district court, absent good reason to do otherwise, should ordinarily decide the 12(b)(1) motion first." De La Cruz v. Irizarry, 946 F.Supp.2d 244, 249 (1st Cir. 2013)(quoting Northeast Erectors Ass'n of BTEA v. Secretary of Labor, Occupational Safety & Health Admin., 62 F.3d 37, 39 (1st Cir.1995) (citing 5A Charles Wright & Arthur Miller, Federal Practice and Procedure § 1350, at 210 (1990)).

The standard of review accorded a dismissal under either Rule 12(b)(1) or 12(b)(6) is "similar." Murphy v. United States, 45 F.3d 520, 522 (1st Cir. 1995). Accordingly, in considering a motion to dismiss a complaint the Court must construe the complaint in the light most favorable to the plaintiff, taking all well-pleaded facts as true, and giving the plaintiff the benefit of all reasonable inferences. Arruda v. Sears, Roebuck & Co., 310 F.3d 13 (1st Cir. 2002). In order to withstand a motion to dismiss, a claim "must contain sufficient factual matter ... to state a claim to relief that is plausible on its face." Katz v. Pershing, LLC, 672 F.3d 64, 72-73 (1st Cir. 2012)(citations omitted). The complaining party must include "factual content that allows the court to draw a reasonable inference" in the pleader's favor. Id. "If, under any theory, the allegations are

sufficient to state a cause of action in accordance with the law," the motion to dismiss must be denied. Vartanian v. Monsanto Co., 14 F.3d 697, 700 (1st Cir.1994). The Court ignores, however, "statements in the complaint that simply offer legal labels and conclusions or merely rehash cause-of-action-elements." Schatz v. Republican State Leadership Comm., 669 F.3d 50, 55 (1st Cir. 2012). In addition, "the party invoking the jurisdiction of a federal court carries the burden of proving its existence." Johansen v. United States, 506 F.3d 65, 68 (1st Cir.2007).

In a case alleging fraud or mistake, Federal Rule 9 requires that a party "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The First Circuit has explained that "'Rule 9 requires specification of the time, place, and content of an alleged false representation, but not the circumstances or evidence from which fraudulent intent could be inferred.'" Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir. 1996)(quoting McGinty v. Beranger Volkswagen, Inc., 633 F.2d 226, 228 (1st Cir.1980), and noting that the heightened pleading requirement imposed by Rule 9 is intended to "give notice to defendants of the plaintiffs' claim, to protect defendants whose reputation may be harmed by meritless claims of fraud, to discourage 'strike suits,' and to prevent the filing of suits that simply hope to uncover relevant information during

discovery"). In other words, a plaintiff alleging fraud must "set forth what is false or misleading about a statement, and why it is false." In re GlenFed, Inc. Sec. Litig., 42 F.3d 1541, 1548 (9th Cir.1994) (*en banc*), superseded by statute on other grounds as stated in Ronconi v. Larkin, 253 F.3d 423, 429 n. 6 (9th Cir.2001).

Although the Court generally may not consider documents outside of the complaint unless it converts the motion to dismiss pursuant to Rule 12(b)(6) into one for summary judgment, it may make an exception "for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to the plaintiffs' claim; or for documents sufficiently referred to in the complaint."[4] Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993). The Court may also consider materials outside the pleadings on a Rule 12(b)(1) motion. Gonzalez v. United States, 284 F.3d 281, 288 (1st Cir. 2002).

## IV. The Parties' Contentions

### A. The Defendants' Position

The Defendants assert that Kaufman's claims are moot, on the

[4] The Court notes that, six weeks after filing her fifteen-page Complaint (Dkt. No. 1), Kaufman submitted ninety pages of exhibits in support of the Complaint (Dkt. No. 4)(Dkt. No. 5 is duplicative). The exhibits, which are also referenced in the Complaint, include the 2012 CVS Caremark annual report and seven medical journal articles related to the effects of taking vitamin E supplements.

grounds that (1) the vitamin E supplement was subject to a money-back guarantee; and (2) CVS made a Rule 68 Offer of Judgment to Kaufman on July 11, 2014, offering to settle her personal claims in full by paying her $730[5], plus costs and reasonable attorneys' fees (Dkt. No. 10-1 at 4-5).(Kaufman rejected the offer on July 24, 2014)(Dkt. No. 10-1 at 7). Following the First Circuit's decision in Bais Yaakov, the Defendants sought to distinguish that case from the instant claim by pointing out that the money-back guarantee on the vitamin E label at issue offered complete relief to Kaufman or any member of the putative class. Defs.' Notice of Decision (Dkt. No. 13) at 2.

Second, the Defendants assert that Kaufman's claims that she was fraudulently induced to purchase vitamin E supplements because of misrepresentations and deceptive advertising on the product label is based entirely on studies which do not support her allegations. Specifically, the Defendants point out that the product label merely states that vitamin E supports heart health and that, at the same time, the label disclaims that the vitamin E supplement cures or prevents disease.

Further, the Defendants suggest that Kaufman's claims are

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[5] The Defendants' offer was calculated on (1) the assumption that Kaufman would have taken two vitamin E supplements a day for ten years, and (2) the current sales price of $8 for the product purchased by Kaufman, plus $2 in taxes. Defs.' Mem. at 9 (Dkt. No. 10).

preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §301 et seq., which precludes states from imposing requirements on nutrition labeling that are not identical to the federal requirements.

The Defendants also assert that Kaufman's claim pursuant to the NYCPA is exempted thereunder. Finally, with respect to Kaufman's claim for unjust enrichment, the Defendants assert that the claim is duplicative and depends entirely on the success of Kaufman's other claims.

B. Kaufman's Position

Kaufman maintains that she has adequately supported her New York state law claim by "demonstrating the absence of any heart-health benefit from vitamin E." She also suggests that it would be premature to resolve disputed facts regarding the meaning and/or consumer understanding of "heart health." Pltf.'s Obj. (Dkt. No. 11) at Page 6 of 27.

With respect to the Defendants' contention that Kaufman's claims are preempted by the FDCA, Kaufman asserts that (1) her claims under New York Business Law § 349 do not seek to impose requirements inconsistent with the FDCA; and (2) the vitamin E label at issue does not satisfy the requirements necessary to support either "structure/function claims" or "health-related claims" because the Defendants' claims are unsubstantiated, false

and misleading. Id. at Page 6 of 27. Kaufman also asserts that she reasonably believed taking vitamin E would help her heart to be well or free from disease but that prevailing science does not support the Defendants' representations on which her belief was based. Id. at Page 10 of 27. With respect to that latter contention, Kaufman points to the medical journal articles attached to her Complaint, which, according to Kaufman, reveal that vitamin E does not decrease or prevent heart disease. Id. at 12 - 14 of 27. In essence, Kaufman suggests that her claims pursuant to New York Business Law § 349 are not expressly preempted by the FDCA because the Defendants' "'heart health'" claims are *false and misleading*," and because the Defendants "misrepresent that vitamin E *reduces the risk of heart disease*."Id. at Page 17 of 27.

Kaufman further asserts that she has not yet had sufficient opportunity to develop a record in support of class certification and that the Defendants's Rule 68 Offer of judgment constitutes an attempt to "pick off" the claims of a representative plaintiff in order to moot the putative class action. Id. at Page 22 of 27. In response to the Defendants' suggestion—following the decision in Bais-Yaakov—that the money-back guarantee on the vitamin E label offers complete relief to Kaufman and the putative class, Kaufman suggest that the guarantee fails to provide for

injunctive relief, attorney's fees, and statutory and punitive damages. Pltf.'s Response (Dkt. No. 15) at 2. Finally, Kaufman maintains that she has pleaded sufficient facts to establish a claim for unjust enrichment. Id. at Page 25 of 27.

It is noted that both parties took the opportunity within their supplemental briefing to apprise the Court of additional case law development after the parties filed their primary memoranda in 2014. Pltf.'s Supplemental Brief (Dkt. No. 19) and Defs.' Response (Dkt. No. 22). Even as late as last week, Kaufman filed a notice of supplementary authority (Dkt. No. 24).

**V. Discussion**

(A) Existing Case and Controversy

In light of the First Circuit Court's determination in Bais Yaakov, this Court's jurisdiction over Kaufman's claims after her rejection of the Defendants' Rule 68 offer is no longer in question. Although the Defendants maintain that, given the money-back guarantee on the product label at issue, there is no actual case or controversy to be resolved in this case, relevant case law indicates otherwise. See, e.g. F.T.C. v. Pantron I Corp., 33 F.3d 1088, 1103 (9th Cir. 1994)(holding that "the existence of a money-back guarantee is insufficient reason as a matter of law to preclude a monetary remedy."); Montgomery Ward & Co. v. F.T.C., 379 F.2d 666 (7th Cir.1967)(holding that allowing a general

company money-back guarantee policy as a defense "would make the false advertising prohibitions of the Act a nullity. Anything might then be advertised as long as unsatisfied customers were returned their money.")

Kaufman's ability to withstand the Defendants' motion to dismiss the Complaint, both on the basis of preemption under the FDCA and for failure to assert a claim upon which relief may be granted, depends on whether she has raised sufficient allegations that the statements on the Defendants' vitamin E product labels constitute misrepresentations. The Court now proceeds to consider Kaufman's claims.

(B) The Nutrition Labeling and Education Act

In 1990, prompted by "concerns from consumer groups about unsubstantiated health claims on food and beverages," Congress passed the Nutrition Labeling and Education Act ("NLEA"), Pub.L. No. 101-535, 104 Stat. 2353 (1990) (codified at 21 U.S.C. § 343 et seq.) Holk v. Snapple Beverage Corp., 575 F.3d 329, 331 (3d Cir.2009). The NLEA's purpose is to " 'clarify and to strengthen [FDA's] authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods.'" Nat'l Council for Improved Health v. Shalala, 122 F.3d 878, 880 (11th Cir.1997) (quoting H.R.Rep. No. 101-538, at 7 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3337).

In other words, "[t]he NLEA places limits on health claims that may be made on food and dietary supplement labels." Id.

(C) No Private Right of Action

The NLEA enforces the FDCA and its regulations; it does not provide for a private right of action. 21 C.F.R. §7.40; Bronson v. Johnson & Johnson, Inc., 2013 WL 1629191 (N.D.Cal. April 16, 2013). See also, Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n. 4, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001) (noting, in the context of the medical device provisions of the FDCA that, due to 21 U.S.C. § 337(a), "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [FDCA]").

(D) FDCA Requirements

Pursuant to 21 U.S.C. § 343(r)(6), a statement for a dietary supplement may be made if--

> (A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,
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> (B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and
>
> (C) the statement contains, prominently displayed and in boldface type, the following: "This statement has

> not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.".
>
> A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made. 21 U.S. § 343(r)(6).

(E) Preemption of State Laws

The NLEA contains an express preemption provision, which states, in relevant part:

> Except as provided in subsection (b),[6] no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce —
>
> . . .
>
> (5) any requirement respecting any claim of the type described in section 343(r)(1) of this title [i.e., nutrition levels and health-related claims], made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title. 21 U.S.C. § 343-1(a)(5).

If a statement for a dietary supplement satisfies FDCA requirements, any consumer fraud claims under state law are precluded. Trujillo v. Walgreen Co., 2013 WL 4047717 at *1 (N.D. Ill. Aug. 9, 2013)(citing Turek v. General Mills, Inc., 754 F. Supp. 2d 956, 961 (N.D. Ill. 2010)).

(F) This Case

Kaufman's claims result from her single purchase of the Defendants' vitamin E supplement, which features a product label containing the term "Heart Health*" and the statements "Supports Antioxidant Health*" and "Vitamin E helps maintain healthy blood vessels and supports heart health.*" As noted, *supra*, the asterisks refer to a disclaimer that the FDA has not evaluated the statements and that the supplement is "not intended to diagnose, treat, cure or prevent any disease." (Dkt. No. 10-1 at Page 2 of 48).

Kaufman alleges that she and other consumers have been fraudulently induced to purchase vitamin E supplements that do not perform as advertised. Specifically, Kaufman alleges that she was "misled by Defendants' statements to believe its vitamin E Products would reduce her risk of heart disease when they do not." Complaint at ¶ 21. Kaufman's assertions that the representations on the product label at issue are false and misleading are based solely on a selection of studies attached to the Complaint, some of which have concluded that taking a supplement containing vitamin E does not reduce the risk of suffering a cardiovascular event or of dying from cardiovascular disease. According to Kaufman, "the entire premise" of her Complaint is that "CVS's 'heart health' claims are *false and*

*misleading*," Pltf's. Obj. (Dkt. No. 11) at 12, and she suggests that the "Defendants would not violate any FDA regulation if they removed these representations." Complaint ¶ 29.

As Kaufman clarifies in her pleadings, she is asserting a "false structure/function" claim. Pltf.'s Supp. Brief (Dkt. No. 19) at 4. The core of Kaufman's claim is the allegation that the struction/function claims on Defendants' vitamin E product label are "false and misleading" and, therefore, do not meet the requirement under the FDCA that those claims must be "truthful and not misleading." 21 U.S.C. § 343(r)(6)(B). As noted, the sole support for Kaufman's allegation depends on the submitted case studies.

A review of the product label at issue reveals that the statements on the vitamin E label are in compliance with FDCA regulations. The label is limited to asserting that Vitamin E supports antioxidant health, maintains healthy blood vessels, and supports heart health.[6] 12 U.S.C. § 343(r)(6)(A). As such, the role of vitamin E as an antioxidant is substantiated by several of the studies cited by Kaufman:

(1) "The rationale for using [dietary] supplements is supported by many in vitro and animal studies showing that they

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[6] The label further states that Vitamin E supports the immune system, which is an assertion not at issue in this case.

protect against [] damaging cellular mechanisms." Fortmann, Stephen P., et al., Vitamin and Mineral Supplements in the Primary Prevention of Cardiovascular Disease and Cancer: An Updated Systematic Evidence Review for the U.S. Preventive Services Task Force, 159(12) Annals of Internal Medicine 824 (December 17, 2013). Pltf.'s Ex. B.

(2) "Basic research studies suggest that vitamin E, vitamin C, and other antioxidants reduce cardiovascular disease by trapping organic fee radicals, by deactivating excited oxygen molecules, or both, to prevent tissue damage...Some, but not all prospective cohort studies support a role for vitamin E in cardiovascular disease prevention." Sesso, H.D., et al. Vitamins E and C in the Prevention of Cardiovascular Disease in Men. The Physicians' Health Study II Randomized Controlled Trial, 300(18) JAMA 2123 (November 12, 2008), Pltf.'s Ex. C;

(3) "Vitamin E has antioxidant properties, including inhibition of oxidation of low-density lipoprotein cholesterol in plasma, leading to the hypothesis that it can prevent these chronic diseases. In some, but not all, basic research reports, vitamin E supplementation retarded atherogenesis [formation of abnormal fatty deposits in an artery]." Lee, I-Min, et al., Vitamin E in the Primary Prevention of Cardiovascular Disease and Cancer. The Women's Health Study: A Randomized Controlled Trial,

294(1) JAMA 56 (July 6, 2005), Pltf.'s Ex. D;

(4) "In humans, [Vitamin E] can improve endothelial [the inner lining of blood vessels] function. Epidemiological data indicate an inverse association between cardiovascular risk and vitamin E intake from dietary sources and/or supplements." Lonn, E., et al., Effect of Long-term Vitamin E Supplementation on Cardiovascular Events and Cancer: A randomized Controlled Trial, 293(11) JAMA 1338 (March 16, 2005), Pltf.'s Ex. E.

It is noted that, with the exception of the Lee study—which itself acknowledged that its finding of a "26% reduction in major cardiovascular events observed among women aged at least 65 years assigned to vitamin E" could have been "due to chance, arising from multiple comparisons"—each of the studies cited by Kaufman ultimately concluded that the taking of vitamin E supplements provided no benefit for the prevention of cancer or cardiovascular disease or the reduction of risk of major cardiovascular events, including heart failure and death. In addition, at least one study concluded that high-dosage (400 IU/d) vitamin E supplements may increase all-cause mortality and should be avoided. Miller, Edgar R. III, et. al, Meta-Analysis: High-Dosage Vitamin E Supplementation May Increase All-Mortality, 142(1) Annals of Internal Medicine 37 (January 4, 2005).

The statements on the Defendants' product label, however,

make no assertions that conflict with these findings. The specific disclaimer that the Defendants' supplement "is not intended to diagnose, treat, cure or prevent any disease," complies with FDCA requirements. The results of these cited studies cannot support a finding of misrepresentation by the Defendants for the limited content of their function/structure claims, which is, moreover, supported by the same studies.

Although Kaufman concedes that the FDCA expressly preempts state laws that seek to impose requirements not identical to those set forth in the NLEA, she suggests that the prohibition against deceptive acts or practices under Section 349 of New York General Business Law, "mirrors" federal requirements that structure/function claims be "truthful and not misleading." Pltf.'s Obj. at 12. In other words, Kaufman suggests that, because the Defendants' labeling is insufficient under the FDCA, it provides grounds for a claim under New York state law that is not preempted by federal law.

Neither Kaufman's allegations nor the studies on which she relies support such a conclusion. The label on the Defendants' Vitamin E products is in compliance with FDCA regulation. Kaufman's allegations that "Defendants misled consumers to believe these products protect consumers' hearts and/or reduce consumer's risk of heart disease;" and that she "was misled by

Defendants' statements to believe its [sic] vitamin E products would reduce her risk of heart disease" are inconsistent with the statements that are actually written on the label, and they are in direct contravention of the explicit disclaimer on the product label.

In sum, Kaufman fails to connect her claims regarding the alleged misrepresentations on the Defendants' vitamin E label with the findings in the clinical studies on which she relies. The label on the vitamin E supplement Kaufman purchased states that vitamin E helps maintain healthy blood vessels and supports heart health. However, the submitted selection of studies, on which Kaufman relies for her misrepresentation claims, investigated the benefits of taking vitamin supplements in the primary prevention of cardiovascular disease and/or cancer. As such, the results of the studies fail to refute the statements on the vitamin E label. Moreover, the Defendants' vitamin E label explicitly states that the product itself is not intended to diagnose, treat, cure or prevent any disease, making the ultimate conclusions of the cited studies irrelevant. In addition, several of the studies cited by Kaufman support, rather than refute, the representations on the Defendants' product label. Under those circumstances, the Court concludes that Kaufman has failed to allege that the representations on the product label are false

and misleading. Accordingly, Kaufman's claims are both preempted by the FDCA and insufficient to state a claim for fraud. In the absence of a viable fraud claim, Kaufman's unjust enrichment claim must fail as well.

**Conclusion**

For the reasons stated herein, the Defendants' motion to dismiss the Complaint is GRANTED and the Complaint is DISMISSED with prejudice[7].

SO ORDERED.

/s/ Mary M. Lisi

Mary M. Lisi
Senior United States District Judge
January 27, 2016

[7] The Court has considered Kaufman's argument in favor of amending her Complaint for further clarification that Defendants' heart health structure/function claims are simply false. In light of the foregoing, the Court finds that an amendment would be futile.